

REMARKS

Please reconsider this application in view of the above amendments and the following remarks.

Claims 1-10, 13-19 and 21-45 are pending.

Claims 1-10, 13-19, and 21-45 are rejected under 35 U.S.C. 103(a) as being unpatentable over Lazorov (6,110,204) in view of Cavasin (5,800,747) and Kirkpatrick et al. (6,676,989).

Lazarov is directed to reduction of blood coagulation and thrombi on medical device surfaces (Col 2, lines 7-11: "Therefore it is the object of the present invention to provide an implant . . . with a surface by which the activation of blood coagulation accompanies by the formation of thrombi as well as the formation of a biofilm are reduced significantly.") Lazarov fulfills this objective by **covering the surface** of the medical device with a coating consisting of group IVA metals, nitrogen and oxygen. The Examiner concedes that Lazarov fails to teach or suggest implanting on a molecular or atomic level at a depth within at least a region of a surface of the stent. However, according to the Examiner, it would have been obvious to one skilled in the art to look at a semiconductor mold-packaging application of Cavasin and a stent cleaning process of Kirkpatrick to modify the Lazarov invention to derive the claims of the present invention. Applicants respectfully submit that the Examiner's reasoning is not only logically flawed but also in direct contrast to well established case law. Applicants submit the following arguments:

1. Lazarov's invention is for **coating the surface** of the medical device to prevent blood and biological tissues from contacting the surface. Applicants respectfully submit, why would one skilled in the art be motivated to implant the coating material within the surface, as opposed to on top of the surface, since implanting within the surface would expose the surface? Isn't preventing the surface from being exposed the objective of Lazarov? Yet according to the Examiner, it would be obvious for one skilled in the art to implant within the surface and leave the surface exposed even though Lazarov's invention is directed to preventing the surface from being exposed.

The Examiner asserts that one skilled in the art would be motivated to do **directly opposite** of what Lazarov teaches since one skilled in the art would be motivated to achieve a blood compatible surface. Lazarov teaches that the surface has to be coated or

covered and not exposed in order to produce a blood compatible surface. Implantation into the surface would leave the surface exposed and not covered, which would form a blood incompatible surface - a direct contradiction to Lazarov's disclosure.

The Examiner also asserts that one skilled in the art would be motivated to implant the coating material of Lazarov into the surface to enhance the stent strength. This basis for support is grossly flawed. Enhancing the strength of the stent by way of Cava-sin is not necessarily advantageous to a stent, as asserted by the Examiner. Stents are deformable structures, subject to bending, expanding, contracting, cyclic loading or similar stresses. "Strengthening" a stent can lead to cracking of the stent under such stress, preventing the stent from being crimped on a delivery balloon, and preventing the stent from being delivered through blood vessels. Moreover, none of the references mention strength enhancement of a stent, which would motivate one of skill in the art to make a stent stronger. Accordingly, the Examiner's underlying basis that one skilled in the art is motivated to strengthen a stent is technically deficient, void of any factual support, and grossly unreasonable.

2. The case law is very clear that if the proposed modification would render the prior art invention being modified unsatisfactory for its intended purpose, then there is no suggestion or motivation to make the proposed modification (*In re Gordon*, 733 F.2d 900, 221 USPQ 1125 (Fed. Cir. 1984)). As indicated by Lazarov, the intended purpose of the invention is to cover the surface of the implant with a coating so as to prevent exposure of the implant's surface to blood. The coating is aimed at preventing blood coagulation and thrombi. The Examiner's suggested modification would leave the implant surface of Lazarov exposed and prone to blood coagulation and thrombi, which would be unsatisfactory for its intended purpose.

3. It is improper to combine references where the references teach away from their combination. *In re Grasselli*, 713 F.2d 731, 743, 218 USPQ 769, 779 (Fed. Cir. 1983). Lazarov and Cava-sin teach away from each other. Lazarov teaches depositing a surface coating 2 on an implant having a thickness of 3 μ m (FIG. 1, Col. 6, line 36-39). Again, to avoid any misunderstanding, Lazarov is geared towards surface deposition. In stark contrast, Cava-sin teaches ion implantation (Col. 3, lines 19-23). Cava-sin emphasizes that its approach is superior to prior art methods of depositing films which coat

the mold tool surfaces (Col. 2, lines 17-22), **and that Cavasin's mold is not susceptible to delamination from the underlying mold material as may occur with deposited surface coating materials** (Col. 5, lines 24-27). Simply put, Cavasin specifically teaches **against formation of an "external" coatings, while Lazarov is specifically directed to "external" coatings on the base material.** Clearly, this is a classic example of two references teaching away from one another.

With respect to Kirkpatrick, Applicants are not even sure how to respond since this reference is irrelevant as the Cavasin reference and is directed to surface polishing and etching of stents. Moreover, **Kirkpatrick explicitly states that his invention is greatly different from ion implantation used in the semiconductor industry, yet the Examiner has conveniently overlooked this statement in Kirkpatrick and combined Kirkpatrick with a semiconductor reference, Cavasin.** Kirkpatrick states that its invention "is different from the case of ion implantation which is normally done with conventional ions and where the intent is to penetrate into the material, sometimes penetrating several thousand angstroms, to produce changes in the surface properties of the material." (Col. 3, lines 51-55 as well Col 3, lines 8-25). Cavasin teaches conventional ion implantation of semiconductor molding to change the molding's surface properties. Clearly, this is another classic example of references teaching away from one another.

4. Further, Applicants respectfully submit that it is improper for the Examiner to rely on Cavasin because it is non-analogous prior art. It has been held that "to rely on a reference as a basis for rejection of an applicant's invention, the reference must either be in the field of the applicant's endeavor or, if not, then be reasonably pertinent to the particular problem with which the invention was concerned." *In re Oetiker*, 977 F.2d 1443, 1446 (Fed. Cir. 1992). Cavasin is directed to a molding for semiconductor packaging and therefore should be considered non-analogous art. Moreover, the teachings of Cavasin are not reasonably pertinent to the particular problem with which the invention is concerned. The invention seeks to minimize neointimal hyperplasia and restenosis in stents by implanting compounds at a depth within at least a region of the surface of the stent. In contrast, Cavasin teaches ion implantation in a shallow surface region of the material to create a surface region on a mold for use in packaging a semiconductor device. As such, it is improper to use Cavasin as a prior art reference for the invention.

5. Regarding Claim 7, the Examiner asserts that it would have been an obvious matter of design choice to make a stent from stainless steel. Applicants traverse this assertion since the Examiner has not provided evidence that one of ordinary skill in the art at the time the invention was made would have made such a substitution.

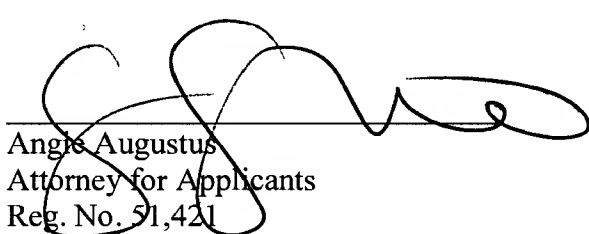
6. Applicants respectfully submit that the Examiner has to duty to adequately address how each claim is rendered anticipated or obvious. The Examiner's one paragraph rejection falls drastically short of such duty and only leaves the Applicant guessing what the rejections could be. For example, with respect to claim 9, the combination of the references fails to teach all of the claimed elements. Claim 9 recites, a "stent comprising a layer of TiN_xO_y or TiN_xC_y on a surface of the stent and a subsurface compound including Ti, N, or TiN disposed beneath the layer of TiN_xO_y or TiN_xC_y , wherein the subsurface compound is intermixed with a surface material of the stent." Nowhere is this construct taught by the references cited by the Examiner.

Removal of the rejection and allowance of the claims is respectfully requested. Applicants do reserve all rights to file an appeal and will do so should this response be followed by another rejection.

Respectfully submitted,

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April 17 2007
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